AMENDMENTS TO THE CLAIMS

Please amend claims 81 and 88. The following listing of the claims will replace all prior versions, and listings, of claims in the application.

1. (Allowed) A process for producing a blood plasma-derived IαIp composition comprising a mixture of inter-alpha inhibitor protein (IαI) and pre-alpha protein (PαI), wherein the IαI and the PαI are present in said mixture in a physiological proportion, the process comprising:

isolating from blood plasma a plasma fraction containing IαI and PαI, wherein the IαI and PαI are present in a physiological proportion; and

purifying the plasma fraction to obtain an IαIp composition with a purity of IαIp ranging from about 85% to about 100% pure, wherein the purifying comprises hydroxylapatite chromatography.

2. (Allowed) The process of claim 1, wherein the isolating comprises solid phase extraction or chromatographing blood plasma.

3-9. (Canceled)

10. (Previously presented) The process of claim 1, wherein the plasma fraction comprises a side fraction obtained from the purification of clotting factor IX or from the purification of a prothrombin complex concentrate.

11. (Canceled)

12. (Allowed) The process of claim 1, wherein the plasma fraction is isolated as a cryosupernatant resulting from cryoprecipitation of blood plasma.

13. (Allowed) The process of claim 1, wherein the plasma fraction is cryo-poor

plasma.

14. (Allowed) The process of claim 1, wherein the plasma fraction is human, primate, bovine, porcine, feline, or canine.

15. (Allowed) The process of claim 1, further comprising obtaining blood, obtaining blood plasma, obtaining a side fraction obtained from the purification of clotting factor IX, obtaining a side fraction from the purification of a prothrombin complex concentrate, obtaining a cryosupernatant resulting from cryoprecipitation of blood plasma or obtaining cryo-poor plasma.

16-20. (Canceled)

21. (Allowed) The process of claim 1, wherein the purifying further comprises affinity chromatography.

22-24. (Canceled)

25. (Allowed) The process of claim 1, wherein the Iαl and Pαl present in the plasma fraction have an apparent molecular weight of between about 60,000 to about 280,000 kDa.

26. (Canceled)

27. (Allowed) The process of claim 1, further comprising: purifying the plasma fraction; virus inactivating the plasma fraction and/or the purified Iαlp; the addition of stabilizers; pasteurization of the purified Iαlp; or anion-exchange chromatography of the purified Iαlp.

28. (Allowed) The process of claim 27, wherein the further purifying the plasma fraction is by passing through heparin affinity column and collecting the flow through (unbound) fraction; the virus inactivating is by a solvent/detergent treatment or thermal inactivation; and the anion-exchange chromatography of the purified IαIp is diethylaminoethyl (DEAE) Sepharose.

29-30. (Canceled)

31. (Allowed) The process of claim 28, wherein the thermal inactivation comprises pasteurization at a temperature of between about 55 to about 65°C. or dry heat at 70 to 120°C.

32-46. (Canceled)

47. (Allowed) A composition of IαIp comprising a mixture of inter-alpha inhibitor protein (IαI) and pre-alpha protein (PαI), wherein the IαI and the PαI are present in said mixture in a physiological proportion and: have a high trypsin inhibitory specific activity between about 1000 to about 2000 IU/mg; have a half life of greater than one hour; comprise a light chain of inter-alpha inhibitor protein associated with at least one of three heavy chains H1, H2 and H3; or comprise a light chain of inter-alpha inhibitor protein associated with at least one of three heavy chains H1, H2, H3 and H4.

48. (Allowed) The composition of claim 47, wherein the trypsin inhibitory specific activity is between about 1400 to about 2000 IU/mg.

49-55. (Canceled)

56. (Allowed) The composition of claim 47, wherein the IαIp composition has a half life of at least 5 hours.

57. (Allowed) The composition of claim 47, wherein the IαIp composition has a half life of at least 10 hours.

58-76. (Canceled)

77. (Allowed) A composition of IαIp comprising a mixture of inter-alpha inhibitor protein (IαI) and pre-alpha protein (PαI), wherein the IαI and the PαI are present in said mixture in a physiological proportion, said composition having been prepared by the process according to claim 1.

78. (Allowed) The composition of claim 77, further comprising an additional therapeutic agent.

79. (Allowed) The composition of claim 78, wherein the additional therapeutic agent is an anti-inflammatory agent, an anti-coagulant or an immunomodulator.

80. (Allowed) A pharmaceutical composition comprising a therapeutically effective amount of the composition of claim 77, and a pharmaceutically acceptable carrier.

81. (Currently amended) A method of treating an inflammation related disorder comprising, administering to a subject in need thereof a therapeutically effective amount of the composition of claim 77, wherein the inflammation related disorder is selected from an acute inflammatory disease, sepsis, septic shock, rheumatoid arthritis, meningitis, an inflammatory bowel disease, Crohn's disease, chronic ~~obstructed~~ obstructive pulmonary disease, and rhinitis.

82. (Canceled)

83. (Canceled)

84. (Original) The method of claim 81, wherein the IαIp is administered as a tablet, capsule, or injectables.

85-87. (Canceled)

88. (Currently amended) A method of treating a subject for acute inflammatory disease, sepsis, septic shock, rheumatoid arthritis, meningitis, an inflammatory bowel disease, Crohn's disease, chronic ~~obstructed~~ obstructive pulmonary disease, and rhinitis in a subject, comprising:

(a) determining the pre-treatment level of one or more of the following levels in a subject:

(i) the level of IαI;

(ii) the level of PαI;

(iii) the level of IαIp;

(iv) the level of H3;

(v) the level of H4;

(vi) the level of H1;

(vii) the level of H2; and

(viii) the level of LC; and

(b) administering a therapeutically effective amount of the composition of claim 77 to the subject.

89-97. (Canceled)

98. (Allowed) A method of monitoring the progress of a subject being treated with an IαIp therapy, comprising:

(a) determining the pre-treatment level of one or more of the following levels, in a subject:

(i) the level of Iαl;

(ii) the level of Pαl;

(iii) the level of Iαlp;

(iv) the level of H3;

(v) the level of H4;

(vi) the level of H1;

(vii) the level of H2; and

(viii) the level of LC;

(b) administering a therapeutically effective amount of the composition of claim 77 to the subject; and

(c) determining the level of one or more of the levels in the subject after an initial period of treatment with the composition,

wherein an increase of the level in the subject following treatment with the composition indicates that the subject is likely to have a favorable clinical response to treatment with Iαlp.

99. (Canceled)

100. (Canceled)

101. (Allowed) A kit comprising a composition according to claim 77 and instructions for therapeutic use.